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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,432	10/27/2003	Kathleen C.M. Campbell	SIU 7399	8934

321	7590	09/14/2007
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102		

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
09/14/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

**Office Action Summary**

Application No.

10/694,432

Applicant(s)

CAMPBELL, KATHLEEN C.M.

Examiner

Leslie A. Royds

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 June 2007 and 12 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 11-13, 15-25 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-13, 15-25 and 27-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12 July 2007
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

**Claims 1-9, 11-13, 15-25 and 27-29 are presented for examination.**

Applicant's Amendment and Terminal Disclaimer (filed over U.S. Patent No. 6,187,817), each filed June 28, 2007, have been received and entered into the present application.

Due to the acceptable nature of the Terminal Disclaimer filed June 28, 2007 over U.S. Patent No. 6,187,817, rejection of claims 1-9, 11-13, 15-25 and 27-29 under the judicially created doctrine of obviousness-type double patenting is hereby withdrawn.

Applicant's Information Disclosure Statement (IDS) filed July 12, 2007 (five pages total) has also been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08a, the Examiner has considered the cited references.

Claims 1-9, 11-13, 15-25 and 27-29 remain pending and under examination. Claim 1 is amended.

Applicant's arguments, filed June 28, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

#### *Claim Rejections - 35 USC § 112, Second Paragraph*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3, 5-9 and 23-24 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, for the reasons of record set forth at pages 2-3 of the previous Office Action dated March 28, 2007, of which said reasons are herein incorporated by reference.

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Applicant traverses the instant rejection, stating that claims 1 and 22 do not require that the patient already be exposed to radiation. Specifically, Applicant states that the claims describe the time and intensity of the radiation by requiring that it be sufficient to result in alopecia, but that the broadest interpretation of the claims does not require any temporal relationship between the administration of the methionine and the radiation exposure.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

Though Applicant alleges that the limitation "in a patient exposed to radiation for a time and at an intensity sufficient to result in alopecia" simply describes the time and intensity of the radiation sufficient to result in the alopecia, Applicant is directed to lines 1-2 of present claims 1 and 22, wherein the claims define the patient in whom the claimed method is practiced by reciting a "method for treating alopecia in a patient exposed to radiation for a time and at an intensity sufficient to result in alopecia" comprising the oral or parenteral administration of an effective amount of methionine. In particular, the use of the word "exposed" clearly indicates that the patient *has already been* exposed to radiation for a time and at intensity sufficient to result in the alopecia. This interpretation of the claims is supported by the fact that the term "exposed" is the past tense form of the verb 'expose' and, thus, is clearly indicative of the patient having already been exposed to the radiation. As a result, the administration of the methionine prior to, or even simultaneously with, the radiation exposure encompasses administration scenarios that are impossible to execute because it would be generally impossible to administer the methionine prior to (or simultaneously with) the radiation exposure if the patient has already been exposed to the radiation. Accordingly, the rejection remains proper despite Applicant's remarks to the contrary.

For these reasons, and those previously made of record at pages 2-3 of the previous Office Action dated March 28, 2007, rejection of claims 2-3, 5-9 and 23-24 remains proper and is maintained.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 11-13, 15-22, 25 and 27-29 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Dye (U.S. Patent No. 5,122,369; 1992) in view of Jacobs et al. ("Treatment of Radiation-Induced Alopecia", *Head Neck Surg*, 1979; 2(2):154-159, Abstract Only), each already of record, for the reasons of record set forth at pages 3-5 of the previous Office Action dated March 28, 2007, of which said reasons are herein incorporated by reference.

For clarity of the record, Applicant is again reminded that present claims 2-3, 5-9 and 23-24 were not included in the present rejection because they fail to further limit the subject matter of the parent claim from which they depend for the reasons described in the rejection *supra* and also because they are directed to an administration scenario that is not possible to execute (i.e., because it would be impossible to administer the protective agent prior to radiation exposure if the patient of the independent claim must have already been exposed to the radiation to induce the alopecia).

Applicant traverses the instant rejection, stating that the Dye reference relates to natural hair loss, nor hair loss caused by treatment with radiation. Applicant further relies upon the fact that Dye teaches a three-phase natural hair loss cycle, including an anagen phase, catagen phase and telogen phase, with a corresponding increase in follicular calcium concentration across the three phases, and alleges that there is no reference of record that would provide a reason to believe that hair loss from causes other than the natural pilar cycle would also exhibit this same increased follicular calcium concentration. Applicant relies upon the reference to Song et al. (*American Journal of Pathology*, 1999, 155(4), p.1121-1127) in support of the assertion that radiation-induced alopecia involves p53 and apoptosis in the follicular

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matrix, which is different than the natural hair cycle. Applicant further alleges that Jacobs et al. is directed to the treatment of radiation-induced alopecia using punch graft hair transplantation and would only have suggested to the skilled artisan that hair transplantation was the best treatment approach. Applicant asserts that neither Dye nor Jacobs provides a reason to combine the disclosures together, since Jacobs fails to suggest a chemical solution to radiation-induced alopecia (because it teaches surgical hair transplantation) and Dye fails to provide any reason that controlling calcium concentrations in hair follicles would have affected radiation-induced alopecia.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

First, Applicant relies upon the reference to Song et al. that allegedly provides evidence that radiation-induced alopecia is caused by p53 activity and apoptosis in the follicular matrix and not increased calcium concentrations as taught by Dye. However, the Office Action declines consideration of such evidence since it was not available to those skilled in the art at the time this application was filed. As noted at pages 3-4 of the Office Action dated March 8, 2006, the instant claims are entitled to the effective filing date of April 8, 1998, which is prior to publication of the Song et al. reference. Accordingly, such post-filing date evidence is not persuasive in establishing nonobviousness, since the determination of obviousness or non-obviousness must be based upon what was known in the art at the time the invention was made. Please see 35 U.S.C. 103, which states, "A patent may not be obtained...if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art" (emphasis added).

In the absence of any evidence supportive of Applicant's allegation that the art *at the time of the invention* recognized an etiological and pathophysiological difference between radiation-induced alopecia and natural hair loss, Applicant's assertions that the therapy disclosed by Dye (i.e., administration of a

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nutrient composition comprising d,l-methionine, pantothenic acid and divalent iron) is not suggestive of the same efficacy in treating alopecia induced by radiation are not persuasive. Such statements amount to no more than allegations without factual support that the two conditions are not one and the same. Please see, e.g., MPEP §716.01(c)[R-2](II), which states, "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965)."

Accordingly, Applicant has failed to rebut the rationale and teachings presented in the rejection of record over Dye in view of Jacobs et al. that the efficacy of the nutrient composition of Dye, containing d,l-methionine, pantothenic acid and divalent iron, for treating natural alopecia would not also have the same, or at least substantially similar, level of efficacy in treating alopecia induced by radiation exposure, such as, e.g., patients undergoing radiotherapy for cancer (as evidenced by Jacobs et al.), due to the clear efficacy of such a composition in decreasing hair lost and slowing alopecia progression, as evidenced by Dye. In view of such, the rejection clearly remains proper for the reasons already of record, which will not be repeated herein so as not to burden the record.

Moreover, Applicant alleges that Jacobs et al. would only have suggested to the skilled artisan to employ hair transplantation to treat radiation-induced alopecia, but fails to address the combined teachings of Dye in view of Jacob et al. as a whole. Jacobs et al. was not relied upon for its teachings of hair transplantation in patients suffering from radiation-induced alopecia, but rather was cited for its teaching that alopecia occurs in patients exposed to radiation, such as, e.g., patients undergoing radiotherapy for cancer. Applicant's focus on the discrete teachings of the cited references fails to appreciate that the references that comprise the rejection are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the combination of the cited references. Please reference *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968) and *In re*

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*Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Moreover, rejections under 35 U.S.C. 103(a) are based upon combinations of references, where the secondary references are cited to reconcile the deficiencies of the primary reference with the knowledge generally available to one of ordinary skill in the art to show that the differences between Applicant's invention and the prior art are such that they would have been modifications that were *prima facie* obvious to the skilled artisan. It is noted that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather the test is in what the combined teachings of the references would have suggested to those of ordinary skill in the art. Please see also *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In view of such arguments regarding the discrete teachings of each of the references without considering the combination as a whole are not persuasive and will not be further considered herein.

For these reasons, and those previously made of record at pages 3-5 of the previous Office Action dated March 28, 2007, rejection of claims 1, 4, 11-13, 15-22, 25 and 27-29 remains proper and is **maintained**.

### ***Double Patenting***

#### **Obviousness-Type Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).



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Claims 1-9, 11-13, 15-25 and 27-29 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent Application No. 11/539,975 in view of The Merck Index (Eleventh Edition, 1989; Monograph 5896, Page 943), each already of record, for the reasons of record set forth at pages 6-8 of the previous Office Action dated March 28, 2007, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that the instant application was filed prior to the '975 application and that the rejection should be withdrawn once the instant application is otherwise in condition for allowance.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

In view of the fact that allowable subject matter has not been identified at the present time in the instant application, and further in view of the fact that Applicant presents no arguments or Terminal Disclaimers regarding this obviousness-type double patenting rejection of record, the rejection remains proper for the reasons set forth at pages 6-8 of the previous Office Action and is, therefore, **maintained**.

#### ***Conclusion***

Rejection of claims 1-9, 11-13, 15-25 and 27-29 remains proper and is herein **maintained**.

No claims of the present application are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the

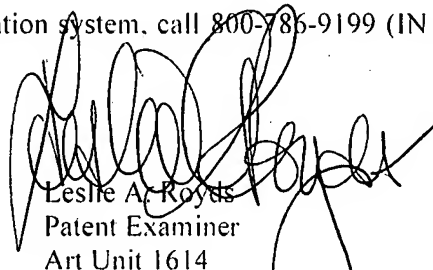
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advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-785-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie A. Royds  
Patent Examiner  
Art Unit 1614

September 4, 2007



ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER